

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS
TITLE 17. PUBLIC HEALTH
DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
CHAPTER 4. PREVENTIVE MEDICAL SERVICE
SUBCHAPTER 9. TESTING FOR HERITABLE DISORDERS
GROUP 3. NEWBORN SCREENING PROGRAM
(AMENDED and/or ADDED SECTIONS IN REGS PACKAGE DPH 09-010E)

ARTICLE 1. DEFINITIONS

§6500. Birth Attendant.

"Birth attendant" means any person licensed or certified by the State to provide maternity care and to deliver pregnant women or to practice medicine.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.03. California Children's Services (CCS).

"California Children's Services (CCS)" means a State and County program providing medically necessary benefits as defined in Title 22, Division 2, Subdivision 7, Chapter 1, §41452 to persons under 21 years of age with physically handicapping conditions who meet medical, financial and residential eligibility requirements for the CCS program.

NOTE: Authority cited: Sections 20, 100275, 123805, 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 123830, 123835, 123845, 123865, 123870, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.05. Confirmatory Test.

"Confirmatory Test" means a laboratory test done to prove or disprove the presence of a specific condition identified by the newborn screening test. This test is performed on a specimen other than the screening specimen.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.1. Days of Age.

"Days of age" means the measurement of the age of a newborn in 24-hour periods so that a newborn is one day of age 24 hours following the hour of birth.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.5. Discharge.

"Discharge" means release of the newborn from care and custody of the perinatal licensed health facility to the parents or into the community.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.9. Early Specimen.

"Early Specimen" means a newborn screening specimen collected from a newborn who is less than 12 hours of age.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.19. Inadequate Specimen.

"Inadequate specimen" means a newborn's blood specimen which is not suitable in quality or quantity to perform newborn screening for one or more of the disorders covered by this Group.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.21. Infant.

"Infant" means a child 29 days through 12 months old.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.25. Initial Positive Test.

"Initial positive test" means a newborn's blood specimen which identified as positive for reporting purposes.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.28. Initial Specimen.

"Initial specimen" means the first specimen collected subsequent to birth, pursuant to this Group.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code. Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.31. Initial Test.

"Initial test" means the first valid newborn screening test or combination of tests of a newborn for each disorder covered by this Group.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.33. Lost to Follow-Up.

"Lost to Follow-Up" means the inability of the Newborn Screening Area Service Center to locate the newborn or infant for follow-up because:

(a) there is no response to attempts to locate the parents or legal guardian after a minimum of 1 phone call and 1 certified letter using available contact information and

(b) the Newborn Screening Area Service Center and the Department believe that reasonable attempts have been made to locate the infant.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.35. Newborn.

"Newborn" means a child less than 29 days old.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.39. Newborn's Physician.

"Newborn's Physician" means the physician caring for the newborn or infant in the perinatal licensed health facility's normal newborn nursery or neonatal intensive care unit or in the outpatient community after discharge.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.43. Newborn Screening.

"Newborn Screening" means the testing of infants to identify those at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.45. Newborn Screening Area Service Center.

"Newborn Screening Area Service Center" means a facility which is contracted with the Department to provide regional newborn screening services.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.46. Newborn Screening Laboratory.

"Newborn screening laboratory" means a laboratory operated by the Department or a laboratory contracting with the Department to conduct tests required by this Group.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.50. Newborn Screening Specimen.

"Newborn Screening Specimen" means a blood sample taken from an infant that is collected on a special filter paper purchased from the Department.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.51. Newborn Screening Test.

"Newborn Screening Test" means a biochemical or other assay of blood spots collected from an infant for the purpose of determining whether the newborn might be at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.55. Out-of-Hospital Newborn Screening Providers.

“Out-of-Hospital Newborn Screening Providers” means:

(a) all healthcare professionals including, but not limited to, licensed midwives (LM), certified nurse midwives (CNM), registered nurses (RN), physician assistants (PA), pediatric nurse practitioners (PNP), physicians/medical doctors (MD), doctors of osteopathy (DO), and naturopathic doctors (ND), who are licensed or certified by the State to provide maternal care and to deliver pregnant women in alternative settings other than perinatal licensed health facilities including, but not limited to, private homes and clinics and

(b) staff of health care entities, such as clinics and free-standing independent laboratories that are authorized by the Department to collect newborn screening specimens in alternative settings other than perinatal licensed health facilities.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.57. Perinatal Licensed Health Facility.

“Perinatal licensed health facility” means any health facility licensed by the State and approved to provide perinatal, delivery, newborn intensive care, newborn nursery or pediatric services.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.58. Perinatal Licensed Health Facility Staff.

“Perinatal Licensed Health Facility Staff” means the individuals working in the laboratory, maternal, or nursery departments of perinatal licensed health facilities who collect the newborn screening specimens.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.59. Preventable Heritable or Congenital Disorder.

“Preventable heritable or congenital disorder” means any disorder or abnormality present at birth which is detectable by testing a newborn and for which effective means of prevention or amelioration exists.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.69. Repeat Specimen.

“Repeat specimen” means a specimen collected from a newborn following the newborn screening laboratory's report that a previously collected specimen was either inadequate or that test results were inconclusive.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.70. Repeat Test.

“Repeat test” means a test required by this Group to be repeated for a newborn because the previous specimen or test results were inadequate or test results were not complete.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6500.71. Screening Information System (SIS).

"Screening Information System (SIS)", in this Group, means the Department Newborn Screening Program's database and associated screens that:

- (a) list the newborn screening specimens that have been received by the Department for testing and
- (b) provide for reporting of those specimens that are missing.

This system is to be used to verify receipt of specimens and report those that have not been received pursuant to §6506.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.74. Sickie Cell Counselor.

"Sickle cell counselor" means a person who:

- (a) is a physician, or has a master's degree in genetic counseling and is board eligible or board certified by the American Board of Genetic Counseling, or is certified by the Department of Public Health as having successfully completed an approved sickle cell counselor training program; and
- (b) Provides face to face information on the medical, social, and genetic consequences of sickle cell disease and trait.

NOTE: Authority cited: Sections 124980 and 125000 and 131200, Health and Safety Code.

Reference: Sections 124980, 125000 and 125025, 131050, 131051 and 131052, Health and Safety Code.

§6500.77. Sickie Cell Education and Counseling Program.

"Sickle cell education and counseling program" means an educational and counseling program in which the disease orientation is, in whole or in major part, sickle cell disease.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124980, 125000, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6500.78. This Group.

"This Group" means Group 3. Newborn Screening Program in the Official California Code of Regulations as follows: Title 17, Public Health, Division 1. State Department of Health Services, Chapter 4, Preventive Medical Service, Subchapter 9. Testing for Heritable Disorders, Group 3. Newborn Screening Program.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

§6500.80. Transfer.

"Transfer" means release of the newborn from care and custody of one perinatal licensed health facility to care and custody of another perinatal licensed health facility, or admission to another perinatal licensed health facility of a newborn from an out-of-state facility.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

ARTICLE 2. TESTING AND FOLLOW-UP PROGRAM REQUIREMENTS

§6501. Scope of Newborn Testing.

Except for provisions in §6501.2 and §6502, each newborn born in California shall be tested for galactosemia, hereditary hemoglobinopathies, phenylketonuria, primary congenital hypothyroidism and disorders authorized for testing in Health and Safety Codes 124977, 124980 and 125001 in accordance with procedures in this Group.

NOTE: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6501.2. Religious Objection.

(a) The provisions of Section 6501 shall not apply if a parent or legally appointed guardian objects to a test on the ground that it conflicts with his or her religious beliefs or practices. If the parent or legal guardian refuses to allow the collection of a blood specimen, such refusal shall be: (1) made in writing, (2) signed by a parent or legally appointed guardian, and (3) included in the newborn's medical or hospital record.

(b) Birth attendants or physicians shall provide to parent(s) or legally appointed guardian(s) who object to the test on the basis it is in conflict with their religious beliefs or practices, a refusal form approved by the Department and shall obtain the appropriate signature(s) upon the form. If the parent(s) or legally appointed guardian(s) is unable to read such material, it shall be translated or read to such person(s) in a language understood by such persons.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6501.5. Required Newborn Screening Forms.

The following newborn screening forms from the Department shall be utilized in accordance with provisions in this Group:

(a) For all newborn screening specimen collection pursuant to §6505(a)(1), §6505(a), §6505(b)(1), §6505(b)(2), §6505(c)(1), §6506, §6506.6(a), §6506.6(b)(1) and §6506.6(c)(1): CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D). This form is hereby incorporated by reference.

(b) For parents or legally appointed guardians who object to a newborn screening test pursuant to §6501.2: NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) (6/11) - Spanish version. This form is hereby incorporated by reference.

(c) For perinatal licensed health facility staff or birth attendants who have not obtained a newborn screening specimen pursuant to §6505(a)(4), §6505(b)(4) or §6506.2: HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS – NO) CDPH 4089 (01/11). This form is hereby incorporated by reference.

(d) For county registrars who register infants born outside of a perinatal licensed health facility or who are not attended by a birth attendant pursuant to §6505(d): NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09). This form is hereby incorporated by reference.

NOTE: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6502. Fatal Condition.

The provisions of Section 6501 shall not apply if the newborn has a condition almost certain to be fatal in the first 30 days of life. The prognosis shall be documented in the medical record.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Section 125000, Health and Safety Code.

§6502.1. Confidentiality.

(a) All information, records of interview, written reports, statements, notes, memoranda, or other data procured by an individual, group or research team in the course of any testing under this Group shall be confidential and shall be used solely for the purposes of medical intervention, counseling, or specific research project approved by the Department.

(b) Except as provided by law, such information shall not be exhibited nor disclosed in any way, in whole or in part, by any individual, group, or research team except with the written consent of the person or his/her legally authorized representative unless such data can be made available in a manner which preserves anonymity of the persons tested.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6503. Newborn Screening Laboratory Requirements.

(a) The Department shall designate laboratories and tests to be used for Department required newborn tests. Such laboratories shall be either laboratories operated by the Department for quality control confirmatory and emergency testing or contractor laboratories licensed as clinical laboratories under the Business and Professions Code.

(b) Perinatal licensed health facilities and birth attendants shall submit required specimens to the newborn screening laboratory designated by the Department.

(c) Contract newborn screening laboratories shall be limited to laboratories that shall have submitted a bid acceptable to the Department on a competitive contract to provide laboratory services in sufficient volume to cover all of the newborns born in a geographical area, as defined by the Department, plus an appropriate emergency capacity. The Department will define not more than six areas and may combine areas if necessary to reduce costs or assure statewide coverage.

(d) Notwithstanding (c) above a comprehensive prepaid group practice direct health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available may have a laboratory serving a comprehensive prepaid group practice health care service plan designated a newborn screening laboratory under terms of a written agreement as defined in Section 6508(b) or may provide services in conformity with the terms of a mutually acceptable contract for services.

(e) Newborn screening laboratories shall participate in a proficiency testing program conducted by the Department's laboratory and shall maintain levels of performance acceptable to the Department.

(f) Newborn screening laboratories contracting with the Department shall be subject to on-site inspections and review of laboratory performance of tests and laboratory records.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 125000 and 125001, Health and Safety Code.

§6504. Parent Education: Birth Attendants.

All birth attendants engaged in providing perinatal care shall provide pregnant women, prior to the estimated date of delivery, with a copy of the informational material, entitled "Important Information for Parents," provided by the Department.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 125000 and 125001, Health and Safety Code.

§6504.2. Parent Education: Perinatal Licensed Health Facilities.

Perinatal licensed health facilities shall provide each pregnant woman admitted for delivery with a copy of the informational material provided by the Department, entitled "Important Information for Parents" prior to collection of the blood specimen if such information has not been provided pursuant to Section 6504. If a woman is unable to read such material, it shall be translated or read to her in a language she understands.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 125000 and 125001, Health and Safety Code.

§6504.4. Specimen Collection Forms.

(a) Department approved specimen collection forms shall not be copied, printed, reproduced, acquired, purchased or distributed other than as provided for in this Group.

(b) Such Department approved specimen collection forms shall be fully and accurately completed by birth attendants, perinatal licensed health facilities and laboratories; and a copy shall be filed in each newborn's medical record.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 125000 and 125001, Health and Safety Code.

§6504.6. Record Maintenance.

Perinatal licensed health facilities shall maintain such records as are necessary to assure compliance with this Group and provide the Department with such data as may be periodically required including, but not limited to, information on all newborns discharged or transferred from the facility without collection of a blood specimen. All such information and records shall be confidential, but shall be open to examination by the Department personnel or its designated agents for any purpose directly connected with the administration of the newborn screening program.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 125000 and 125001, Health and Safety Code.

§6505. Collection of Newborn Screening Specimens.

(a) For each newborn born in a perinatal licensed health facility, the perinatal licensed health facility staff shall:

(1) collect the newborn screening specimen, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than 96 hours of age prior to discharge or transfer of the newborn unless the newborn's condition is life-threatening and the collection cannot be done safely. Physicians attending critically ill newborns who require special care may postpone collection of a newborn screening specimen until the newborn's emergency condition is stabilized. The receiving perinatal licensed health facility staff shall then collect the newborn screening specimen using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) as soon as the newborn's condition is stabilized. Any specimen collected on a newborn prior to 12 hours of age is an early specimen and another specimen shall be collected after 12 hours of age pursuant to §6505(a)(2) and §6506.6.

(2) collect a newborn screening specimen prior to red blood cell transfusion when the newborn is stable, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to §6501.5(c), in the event the newborn screening specimen is not collected prior to transfer to another perinatal licensed health facility and there is no copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) in the newborn's medical record.

(5) Collection of a newborn screening specimen under this section shall not apply if the parent or legal guardian has signed a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) pursuant to 6501.5(b).

(b) For infants not born in a perinatal licensed health facility, but admitted to a perinatal licensed health facility at any time after birth, the perinatal licensed facility staff shall:

(1) obtain a newborn screening specimen within 48 hours of admission, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b), unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record or the physician has a record of the screening specimen having been collected.

(2) collect a newborn screening specimen prior to red blood cell transfusion, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to 6501.5(c), in the event the newborn screening specimen is not collected.

(c) For infants not born in a perinatal licensed health facility and not admitted to a perinatal licensed health facility after birth, out-of-hospital newborn screening providers shall:

(1) collect a newborn screening specimen within 48 hours of the first contact with the infant using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record.

(2) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(d) For infants born outside of a perinatal licensed health facility, not attended by a birth attendant, and not subsequently admitted to a perinatal licensed health facility, and when the birth is being registered at the county registrar's office by the parent or legal guardian, the person in the county registrar's office required to register the birth shall notify the Department of the birth the next business day after the birth is registered using the NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09) pursuant to §6501.5(d).

(e) A newborn screening specimen may be collected on a child over 1 year of age with prior authorization from the Department.

(f) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers without identifying the person or persons from whom these results were obtained.

NOTE: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6506. Verification of Receipt of Newborn Screening Specimens by the Department.

(a) Perinatal licensed health facility staff and-out-of-hospital newborn screening providers shall check the Department Screening Information System (SIS) within 7 days after the date of birth to verify that the newborn screening specimen has been received by the Department. This applies to all infants for whom perinatal licensed health facilities and out-of-hospital newborn screening providers have responsibility for newborn screening pursuant to §6505(a), (b) and (c). If a specimen has not been received and there is neither a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) - Spanish version pursuant to §6501.2 and 6501.5(b) present in the newborn's medical record, the staff shall complete a HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS – NO) CDPH 4089 (01/11) pursuant to §6501.5(c). If a specimen has not been received and the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) is present in the newborn's medical record, staff shall enter a missing specimen report into the Screening Information System (SIS), and if the newborn has not been discharged, collect a newborn screening specimen on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) within 24 hours.

This specimen shall be given to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory on the next business day of the designated carrier.

(b) If a perinatal licensed health facility or a group of perinatal licensed health facilities has an internal computerized system in place to identify specimens received by their designated newborn screening laboratory, and this system has the same criteria to verify receipt of newborn screening specimens as the Department's Screening Information System (SIS) as described in §6500.71(a) and (b), then their system rather than SIS may be used to verify receipt of their specimens.

NOTE: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 12500, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6506.2. Newborns Discharged from a Perinatal Licensed Health Facility Without Testing.

(a) Whenever a perinatal licensed health facility determines that a discharged newborn has not received the mandated tests, the facility shall contact the newborn's physician by telephone to inform him/her that a specimen must be obtained and immediately send written notification to the newborn's physician and the Department. If the newborn's physician cannot be contacted or will not obtain a specimen, the perinatal licensed health facility shall notify the Department-approved Newborn Screening Area Service Center by telephone and shall send written notification within five days to the Newborn Screening Area Service Center and the Department.

(b) When the newborn's physician is notified by telephone by the perinatal licensed health facility that a newborn was discharged from the perinatal licensed health facility before a specimen was taken, the newborn's physician shall make every reasonable effort to have a specimen obtained within five days of notification. If the newborn's physician cannot obtain the specimen, the Newborn Screening Area Service Center shall be notified by the newborn's

physician by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6506.6. Follow-Up to Reports of Inadequate and Early Newborn Screening Specimens.

(a) For those specimens identified by the Department as early, or where the infant's age at time of specimen collection cannot be determined, the Newborn Screening Area Service Center shall verify with the collecting person or facility the dates and times of birth and specimen collection written on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D).

(b) Upon notification by the Newborn Screening Area Service Center that the specimen is verified as an early specimen, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(c) When the perinatal licensed health facility staff, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician is notified by the Newborn Screening Area Service Center that a specimen is an inadequate specimen, the perinatal licensed health facility, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(d) If a repeat specimen for either an early or an inadequate specimen cannot be obtained, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall notify the Newborn Screening Area Service Center by phone, fax, or e-mail within 48 hours regarding the status of the collection and also again when the specimen has been collected and sent to the Department.

(e) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

NOTE: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6506.8. Follow-Up to Reports of Positive Results.

(a) When the newborn's physician is notified by a Newborn Screening Area Service Center of a positive test result, the physician shall, within 48 hours of notification:

(1) Consult with a medical specialist from a California Children's Services (CCS) center or a CCS-paneled medical specialist, and upon the specialist's advice, shall refer the infant to a CCS center or a CCS-paneled medical specialist for confirmatory testing and/or evaluation, diagnosis, and treatment, and

(2) Instruct the parents about medically necessary recommendations to care for the infant.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

NOTE: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6506.10. Use of Newborn Screening Contracted Laboratories for Repeat and Confirmatory Specimens.

(a) When repeat or confirmatory tests are required, the physician will ensure that:

- (1) Repeat or confirmatory specimens are collected within 48 hours,
- (2) Specimens are placed in containers appropriate for the specified test, and
- (3) Specimens are transported, on the next business day of the designated carrier, by a carrier contracted with the Department or contracted with a newborn screening laboratory or by the United States Postal Service, to the assigned newborn screening laboratory.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

NOTE: Authority cited: Sections 124977, 124980, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

§6506.12. Diagnosis Reporting.

All physicians making an initial diagnosis of a preventable heritable disorder for which testing is required under this Group shall report such diagnosis and provide the information necessary for follow-up and investigation to the Department.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

§6507. Failure to Comply.

Willful or repeated failure to comply with this Group shall be referred by any person having knowledge of non-compliance to the appropriate licensing authority. Failure to report may constitute grounds for disciplinary action including revocation of license.

Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980, 124985 and 125000, Health and Safety Code.

§6507.1. Local Agency Responsibilities.

(a) The county registrar of births shall provide a copy of the informational material prepared and provided by the Department to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility when the said newborn was not admitted to a perinatal licensed health facility within the first 30 days of age. The local health officer and the Department shall be notified of each such registration by the county registrar.

(b) Each local health department in the county where a newborn resides shall be responsible for making every reasonable effort to obtain specimens when requested by the Department-approved Newborn Screening Area Service Center or the Department. If after every reasonable effort a specimen cannot be obtained, the local health department may, after 30 days, with approval from the Department, terminate efforts.

NOTE: Authority cited: Sections 124980 and 125000, Health and Safety Code.

Reference: Sections 124980 and 125000, Health and Safety Code.

ARTICLE 3. SICKLE CELL PROGRAMS

§6507.2. Sickle Cell Education and Counseling Program Requirements.

(a) Each sickle cell education and counseling program shall apply for and obtain written approval from the Department of Health Services. Such approval shall be contingent upon

compliance with all sections of this Group.

(b) Each sickle cell education and counseling program shall:

- (1) Provide counseling services to the clients.
- (2) Employ State-approved sickle cell counselors to perform all of the counseling following, or relating to, any abnormal hemoglobinopathy finding.
- (3) Demonstrate, upon request by the Department of Health Services, that each of its counselors successfully participates in State-approved educational programs which serve to update the knowledge and enhance the proficiency of such counselors.
- (4) Have a physician with special training and experience in pediatric hematology to serve as medical director or consultant to order and interpret laboratory tests used in counseling.
- (5) Have written protocols to protect the confidentiality and security of all records containing personal information.
- (6) Use only State-approved educational materials.
- (7) Use any laboratory that meets the Department's standards for sickle cell hemoglobin testing.

NOTE: Authority cited: Sections 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 124980, 125000, 125025 and 125030, Health and Safety Code.

§6507.3. Certification of a Sickle Cell Counselor.

(a) A sickle cell counselor shall obtain a certificate of approval from the Department of Health Services upon presentation of written evidence that he or she has:

- (1) Completed a course at a sickle cell counselor training center approved by the Department with such center's endorsement of his or her ability to function as a sickle cell counselor, and/or
- (2) Successfully completed an examination or examinations which demonstrate his or her knowledge or expertise in the field, and one or more personal interviews to demonstrate an understanding of, and ability to communicate with persons who have sickle cell disease or sickle cell trait.

(b) All sickle cell counselors must provide documentation of completion of State-approved training to update skills and knowledge on an annual basis.

(c) This section shall not apply to physicians.

NOTE: Authority cited: Sections 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 125000, 125025 and 125030, Health and Safety Code.

§6507.4. Voluntary Participation.

Participation by any person in a sickle cell education and counseling program in which medical information is obtained through interview, test or other ascertainment procedure shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other services or assistance from, or to participation in any other program.

NOTE: Authority cited: Sections 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 124980, 125000, 125025 and 125030, Health and Safety Code.

§6507.5. Informed Consent.

(a) A sickle cell education and counseling program shall obtain informed consent from each adult upon whom testing or any other screening procedure is to be performed. If the person is a minor other than a newborn, informed consent shall be obtained from such child's parent or guardian. An informed consent shall be obtained from an emancipated minor without the need for parent or guardian consent.

(b) The informed consent shall be in writing in format approved by the Department and shall be signed by the person, by his or her guardian or, except in the case of an emancipated minor, by his or her parent.

NOTE: Authority cited: Section 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 124980, 125000, 125025 and 125030, Health and Safety Code.

§ 6507.6. Approval of Hemoglobin Testing Laboratories.

(a) All laboratories that accept specimens from an approved sickle cell counseling program shall be in compliance with the Business and Professions Code governing licensed clinical laboratory operations and personnel (commencing with Section 1200 of the Business and Professions Code) or be an approved public health laboratory operated in accordance with the California Health and Safety Code, Section 101150 et seq.

(b) All laboratories involved in sickle cell screening as specified in this Article shall use a test or combination of tests with demonstrated ability to distinguish hemoglobins including F, A, S, C, D, and E, as well as the thalassemias.

(c) The State Department of Health Services shall have the responsibility of monitoring sickle cell screening laboratories coming under the scope of this Article. Such monitoring may be accomplished by on-site inspections and proficiency testing, or any other effective method. The Department may deny, revoke, or suspend the approval of any laboratory which does not comply or continue to comply with the above qualifications.

NOTE: Authority cited: Sections 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 124980, 125000, 125025 and 125030, Health and Safety Code.

§6507.7. Sickle Cell Trait Carrier Follow-Up Vendor.

(a) A sickle cell trait follow-up vendor shall mean any sickle cell education and counseling program that:

(1) Is approved under this Group, and

(2) Signs a vendor agreement to provide services in accordance with Department policies, including a fee schedule provided by the Department. The Department may obtain and provide reimbursements for any or all follow-up services authorized as a result of newborn sickle cell screening from such approved vendors.

NOTE: Authority cited: Sections 124980, 125000 and 125025, Health and Safety Code.

Reference: Sections 124980, 125000, 125025 and 125030, Health and Safety Code.

ARTICLE 4. NEWBORN SCREENING PARTICIPATION FEE

§6508. Newborn Screening Fee Collection.

(a) Perinatal licensed health facilities and birth attendants shall obtain from the Department a sufficient supply of specimen collection forms to permit collection of a blood specimen from each newborn required to be tested under this Group.

(b) The Department shall collect a fee for each specimen record form provided and a program participation fee for all services provided. The fee for a specimen form shall be \$1 and for program services shall be \$111.70 except for a comprehensive prepaid group practice direct health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available, which elects to provide testing, follow-up and/or counseling services to its members. The fee for such plans shall be equal to the Department's cost of administration of the newborn screening program, to be determined by reducing the \$111.70 program service fee by the annual statewide average per infant contracted cost of laboratory testing, follow-up and/or counseling services rendered during the previous fiscal year. In order to qualify for this special fee a medical group serving a comprehensive prepaid group practice direct care service plan with 20,000 or more births shall sign a written agreement which contains the same standards and conditions, except as to payment or where specifically waived, as are applicable to the newborn screening laboratories and Newborn Screening Area Service Centers, adhere to the regulations governing the program, and to submit to monitoring and

evaluation of compliance. Failure to comply with these conditions after being given written notification and 30 days to correct deviations shall result in loss of the option. In the event the option is lost the State shall designate appropriate contractors to provide services.

The provisions of this section shall apply even if the newborn is part of a State-approved demonstration project.

(c) Birth attendants and physicians attending newborns who are under six days of age and who were not born in perinatal licensed health facilities and not subsequently admitted to perinatal licensed health facilities shall obtain a sufficient supply of specimen record forms to permit collection or shall arrange for a collection of a blood specimen from each such newborn attended.

(d) Birth attendants and physicians attending newborns and perinatal licensed health facilities shall not charge parents or third parties responsible for medical care coverage fees for participation in the newborn screening program in addition to those specified in this section, except for reasonable fees for costs of blood specimen collection and handling which shall not exceed \$6.

(e) The perinatal licensed health facility shall make available to the responsible physician, at no additional charge, specimen collection services or a specimen record form for obtaining either a repeat specimen for an inadequate specimen or a specimen on a newborn discharged without the test having been obtained.

NOTE: Authority cited: Sections 124977, 124996, 125000, 131050, 131051 and 131200, Health and Safety Code.

Reference: Sections 124977, 124996, 125000 and 125001, Health and Safety Code.